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10/511,016	05/31/2005	Dong-Hyun Kim	008483.P002	8746

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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,016	KIM ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 09/26/2008 with the amendment of claim 1 and the cancellation of claims 4 and 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 2 are currently under examination.

Claim Rejections - 35 USC § 112

Claims 1 and 2 are rejected under USC 112, first paragraph because the claimed invention is not deemed enabled without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological material (newly applied as necessitated by amendment).

It is apparent that the microorganism(s) is/are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. 1.802.

The specification does not provide a repeatable process for obtaining the bacterial strains: *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2, and it is not apparent *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 are readily available to the public. The specification must contain the date that the bacterium/bacteria was/were deposited, the

name of the bacterium/bacteria and the address of where the bacterium/bacteria was/were deposited.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807;

and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. 1.809 (d) should be added to the specification. See 37 C.F.R. 1.803-1.809 for additional explanation of these requirements.

Please note that waving the biological deposit requirement requires fulfillment of one of two-prong conditions: (a) the strain is readily known and available or (b) the strain can be made or isolated without undue experimentation. (See, e.g, 37 CFR 1.802 and MPEP 2404.01-02) The Office will accept commercial availability as evidence that a biological material is known and readily available *only when the evidence is clear and convincing that the public has access to the material* (See MPEP 2404.01). The instant record is unclear in regards to whether the claimed *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 was readily known or available and/or that it could be isolated without undue experimentation. In fact, the strains *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 do not appear anywhere within the texts of the evidence provided by Applicant. Likewise Examiner's search of the patent and non-patent literature did not retrieve any sources citing these particular strains of bacteria. Therefore, it is the position of the Office that the bacterial strains instantly claimed cannot clearly and unequivocally be readily known since the evidence provided by Applicant is not clear and convincing that the public has access to the material.

Please note that the art rejection below is made based on what Applicants are enabled for.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (newly applied as necessitated by amendment).

The metes and bounds of claim 1 are rendered uncertain by the phrase "subsequently drying the organic extract by lyophilization or spray drying wherein the organic extract is subsequently used for preventing or treating a stroke" because it is unclear as to which "organic extract" Applicants are referring to. Applicants have lyophilized or spray-dried the organic extract, which would result in a dried product. Are Applicants referring back to the organic extract prior to the final processing step(s)? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. In addition, a step of using the instantly claimed organic extract (as recited in the last line of amended claim 1) does not properly read upon a method of preparation (which the preamble indicates the claimed invention is drawn to) and, thus, is unclear and indefinite as being outside the limitations of such a preparatory method (accordingly, please note that this intended use limitation has not been given patentable weight - as discussed further below).

Claim Rejections - 35 USC § 103

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto (T*, 03-277247), in view of Lu (N1, CN 1327850 A) (newly applied as necessitated by amendment).

Hashimoto teaches a method of extracting saponins from ginseng, wherein the following portion of ginseng may be used: stems are commonly used from Siberian ginseng and roots from other ginsengs, such as Asian ginseng, American ginseng, and so forth, but the present invention, not limited to these, can use any other portion that contains saponins. Hashimoto further teaches that the method of extracting saponins from ginseng occurs by first crushing, grinding, or extracting ginseng, wherein the extraction may be carried out by mixing shredded, crushed, or ground ginseng with water in a quantity suitable for the application and after the ginseng is extracted with a solvent, such as an alcohol aqueous solution, etc., the solvent is eliminated by vacuum concentration, etc., thereby bringing the ginseng into a condition that allows the proliferation of lactobacillus. Hashimoto further teaches that the thus obtained ginseng processed product, such as the crushed, ground, or extracted product of ginseng, is inoculated with lactobacillus and fermented, but prior to the fermentation, the present invention may add such food ingredients as crushed vegetables or fruits or their juices, dairy products, teas, coffee, cocoa, saccharides, etc., to the ginseng processed product (please note that dairy products, teas, coffee, cocoa, fruits and vegetables are all foods that contain acid and read on acid-containing food). Hashimoto further teaches that the supernatant obtained in the fermentation or the entire fermentation product may be

dried and formed into a powder for use. Hasimoto further teaches that the quantity of crude saponins that were isolated from the supernatant of each fermentation liquid was measured using a SEP-PAK C-18 column and found to be from 2,000 to 2,400 μg/mL for every fermentation liquid, and, compared with that of the non-fermented ginseng liquid, which was 2,570 μg/mL, the decrease of saponins caused by the fermentation was very small in every case. Hashimoto further teaches that crude saponins were isolated from the supernatant of each fermentation liquid and from the supernatant of the non-fermented liquid, after which the isolated crude saponins were isolated by silica gel thin-layer chromatography, which reads on isolating the saponins.

Please note that the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)). Since Applicants claim an extract containing saponins obtained from ginsent and the method taught by Hashimoto also produces an extract containing saponins obtained from ginseng and recites the same method steps as claimed by Applicants, extracting the ginseng with a solvent prior to mixing the ginseng with a source of acid, as taught by Hashimoto, rather than after, as claimed by Applicants, does not change the product.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art

composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Hashimoto does not teach a step of lyophilizing or spray-drying the saponin-containing extract. However, Lu teaches that a saponin-containing extract from American ginseng, which is useful for treating cerebrovascular disease (which reads on stroke), wherein the extract is obtained by extraction with alcohol, subjecting the extract to column chromatography and subsequently spray-drying the saponin-containing extract to provide a high content of ginseng saponins.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Hashimoto by spray-drying the saponin containing extract after purification of the extract with column chromatography to provide the instantly claimed invention because at the time the invention was made, the claimed method steps including drying the saponin-containing product obtained after fermentation with a lactic acid bacteria was known in the art, as

clearly taught by Hashimoto, as was that after subjecting a saponin-containing product obtained from ginseng to spray-drying after column chromatography, as clearly taught by Lu. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Hashimoto to provide the instantly claimed invention because it was known in the art that a saponin-containing extract that had been spray-dried was useful for the purpose claimed by Applicants, as was that spray-drying is a common method of drying saponin-containing extracts of ginseng, as clearly taught by Lu.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to modify the method taught by Hashimoto by spray-drying the saponin containing extract after purification of the extract with column chromatography to provide the instantly claimed invention because at the time the invention was made, the claimed method steps including drying the saponin-containing product obtained after fermentation with a lactic acid bacteria was known in the art, as clearly taught by Hashimoto, as was that after subjecting a saponin-containing product obtained from ginseng to spray-drying after column chromatography, as clearly taught by Lu.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to modify the method taught by Hashimoto by spray-drying the saponin containing extract after purification of the extract with column chromatography to provide the instantly claimed invention because at the time the invention was made, the claimed method steps including drying the saponin-containing product obtained after

fermentation with a lactic acid bacteria was known in the art, as clearly taught by Hashimoto, as was that after subjecting a saponin-containing product obtained from ginseng to spray-drying after column chromatography, as clearly taught by Lu.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any rejections not addressed above have been withdrawn based upon Applicant's newly recited limitations.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark, AU 1655
December 31, 2008

/Christopher R. Tate/
Primary Examiner, Art Unit 1655